

## WHAT IS CLAIMED IS:

1. A method of stabilizing highly purified DNA comprising:
  - 5 a) isolating and purifying DNA to produce the highly purified DNA; and
  - b) optionally, removing metal ions from the purified DNA; and
  - b) introducing the purified DNA into a solution to form a stabilized DNA formulation, the solution being substantially free of metal ions.
- 15 2. The method of claim 1 wherein the solution contains a nonreducing free radical scavenging agent.
3. The method of claim 2 wherein the nonreducing scavenging agent is selected from the group consisting of ethyl alcohol, glycerol, methionine, dimethyl sulfoxide, and combinations thereof.
- 20 4. The method of claim 1 wherein the solution contains a salt.
5. The method of claim 2 wherein the solution contains a salt.
- 25 6. The method of claim 3 wherein the solution contains a salt.
7. The method of claim 1 further comprising the storage of the stabilized DNA formulation in the absence of light.
- 30 8. The method of claim 2 further comprising the storage of the stabilized DNA formulation in the absence of light.

9. The method of claim 4 further comprising the storage of the stabilized DNA formulation in the absence of light.

5 10. A stabilized DNA formulation comprising purified DNA, a nonreducing free radical scavenging agent, a salt and a buffer.

10 11. The formulation of claim 10 wherein the nonreducing free radical scavenging agent is selected from ethanol, glycerol, methionine, dimethyl sulfoxide, and combinations thereof.

12. The formulation of claim 11 wherein the salt is selected from NaCl, KCl, LiCl and combinations thereof.

15 13. The formulation of claim 12 wherein the buffer is selected from Tris-HCl, glycine, sodium phosphate, potassium phosphate, lithium phosphate, sodium succinate, potassium succinate, lithium succinate, sodium malate, potassium malate, lithium malate, sodium bicarbonate, potassium bicarbonate, lithium bicarbonate and  
20 combinations thereof.

14. The method of claim 1 wherein the purified DNA is suitable for human clinical use.

25 15. The method of claim 1 wherein the purified DNA is selected from influenza virus DNA, hepatitis A virus DNA, hepatitis B virus DNA, hepatitis C virus DNA, human papillomavirus DNA, DNA from *Mycobacterium tuberculosis*, human immunodeficiency virus DNA, varicella zoster virus DNA, herpes virus DNA, measles virus  
30 DNA, rotavirus DNA, mumps virus DNA, rubella virus DNA and combinations thereof.

16. A method of stabilizing DNA comprising:
- a) isolating and purifying the DNA to produced purified DNA;
  - b) optionally, removing metal ions from the purified DNA;
  - c) optionally, introducing the purified DNA into a solution to form a stabilized DNA formulation, the solution being substantially free of metal ions;
  - d) placing the purified DNA in a formulation containing an amorphous sugar; and
  - e) lyophilizing the solution.
17. A stable formulation of DNA comprising demetalated DNA and a nonreducing free radical scavenging agent.
18. The formulation of claim 17 which further comprises a salt.
19. The formulation of claim 17 wherein the demetalated DNA is selected from influenza virus DNA, hepatitis A virus DNA, hepatitis B virus DNA, hepatitis C virus DNA, human papillomavirus DNA, DNA from *Mycobacterium tuberculosis*, human immunodeficiency virus DNA, varicella zoster virus DNA, herpes virus DNA, measles virus DNA, rotavirus DNA, mumps virus DNA, rubella virus DNA and combinations thereof.
20. The method of claim 1 wherein the solution contains a metal ion chelator.
21. The method of claim 20 wherein the metal ion chelator is selected from EDTA, DTPA, NTA, inositol hexaphosphate, tripolyphosphate, polyphosphoric acid, sodium succinate, potassium

succinate, lithium succinate, sodium malate, potassium malate, lithium malate and combinations thereof.

22. A stabilized DNA formulation comprising purified  
5 DNA, a nonreducing free radical scavenging agent, a metal ion chelator, a salt and a buffer.

23. A stabilized DNA formulation of claim 22 wherein  
10 the metal ion chelator is selected from the group consisting of EDTA, DTPA, NTA, inositol hexaphosphate, tripolyphosphate, polyphosphoric acid, sodium succinate, potassium succinate, lithium succinate, sodium malate, potassium malate, lithium malate and combinations thereof.

24. A stabilized DNA formulation of claim 23 wherein  
15 the nonreducing free radical scavenging agent is selected from ethanol, glycerol, methionine, dimethyl sulfoxide, and combinations thereof.

25. A stabilized DNA formulation of claim 24 wherein  
20 the metal ion chelator is EDTA and the nonreducing free radical scavenging agent is ethanol.

26. A stabilized DNA formulation of claim 25 wherein  
the salt is selected from NaCl, KCl, LiCl and combinations thereof.

25 27. A stabilized DNA formulation of claim 25 wherein  
the salt is NaCl.

28. A stabilized DNA formulation of claim 26 wherein  
30 the NaCl concentration is from about 100 mM to 200 mM.

28. A stabilized DNA formulation of claim 25 wherein  
the buffer is selected from Tris-HCl, glycine, sodium phosphate,  
potassium phosphate, lithium phosphate, sodium succinate, potassium

succinate, lithium succinate, sodium malate, potassium malate, lithium malate, sodium bicarbonate, potassium bicarbonate, lithium bicarbonate and combinations thereof.

5                    29. A stabilized DNA formulation of claim 28 wherein the buffer is Tris-HCl.

                  30. A stabilized DNA formulation of claim 29 wherein the buffer pH is from about 9.0 to about 9.5 in a glycine buffer.  
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                  30. A stabilized DNA formulation of claim 29 wherein the buffer pH is from about 8.0 to about 9.0 in a Tris-HCl buffer.

                  31. A stabilized DNA formulation of claim 25 wherein  
15 EDTA is present at a concentration up to about 5 mM.

                  32. A stabilized DNA formulation of claim 31 wherein EDTA is present at a concentration up to about 500  $\mu$ M.  
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                  33. A stabilized DNA formulation of claim 25 wherein ethanol is present at a concentration up to about 3%.

                  34. A stabilized DNA formulation of claim 33 wherein  
25 ethanol is present at a concentration up to about 2%.

                  35. A stabilized DNA formulation comprising:  
  
                  (a) a purified DNA;  
30  
  
                  (b) Tris-HCl buffer at a pH from about 8.0 to about 9.0;

(b) ethanol at about 3% w/v;

(c) EDTA in a concentration range up to about 5 mM; and,

5 (d) NaCl at a concentration from about 50 mM to about 500 mM.

10 36. A stabilized DNA formulation of claim 35 wherein the NaCl concentration is from about 100 mM to 200 mM.

37. A stabilized DNA formulation of claim 36 wherein the buffer pH is from about 8.5 to about 9.0.

15 38. A stabilized DNA formulation of claim 37 wherein EDTA is present at a concentration up to about 500  $\mu$ M.

39. A stabilized DNA formulation of claim 38 wherein ethanol is present at a concentration up to about 2%.

20 40. A stabilized DNA formulation of claim 35 wherein EDTA is present at a concentration up to about 500  $\mu$ M.

25 41. A stabilized DNA formulation of claim 40 wherein ethanol is present at a concentration up to about 2%.